

Schedule II Drugs

CVS	Stores	<i>Policy & Procedure</i>
	Pharmacy Operations Manual	
	<i>Policy No. ROPP-0011</i>	
	Date Effective: 8/98	
	Revised: 9/08	

Title: Schedule II Drugs

Purpose: To describe the CVS method of maintaining a perpetual Schedule II Control Drug Inventory while emphasizing the importance of strict adherence to all Federal and State regulations regarding Schedule II drugs.

Procedure:

1. EXPECTATIONS:

1.1. A perpetual inventory for all Schedule II drugs is established and then maintained on a daily basis.

1.2. Any change in the inventory level of a Schedule II drug is documented on that medication's Schedule II Inventory Form.

1.3. Only the pharmacist is to receive, check in, and put away Schedule II orders.

1.4. Only the pharmacist is to retrieve, count, record, and then put away the medication, when a prescription for a Schedule II is filled.

PLAINTIFFS TRIAL
EXHIBIT
P-23305_00001

1.5. All Schedule II prescriptions are double counted and logged prior to dispensing.

1.6. Any discrepancy between the Schedule II Inventory Forms and the physical inventory is reported to the DSM or Pharmacy Supervisor immediately.

1.7. A physical inventory of all Schedule II medications is performed at least once a month by alternating pharmacists.

1.8. The Schedule II Inventory Forms used for the perpetual inventory are never stored in the narcotic (CII) cabinet or in the pharmacy safe.

1.9. Access to the pharmacy safe or narcotic (CII) cabinet is restricted to the registered pharmacist on duty.

1.10. Items other than Schedule II medication, unused DEA 222 forms and personnel records are not kept in the Narcotic safe or Narcotic cabinet.

1.11. All State and Federal Laws regarding to the sale of exempt narcotics are complied with.

2. SCHEDULE II DRUGS

2.1. The security of the store's Schedule II inventory is the responsibility of the pharmacist(s) on duty.

2.2. It is the pharmacist's responsibility to ensure that:

2.2.1. All State and Federal Laws regarding Schedule II drugs are followed.

2.2.2. All CVS policies and procedures regarding Schedule II drugs are followed.

3. SCHEDULE II ORDERS

3.1. The warehouse does not carry Schedule II medications.

3.2. Order all Schedule II medications through the PRIMARY pharmacy wholesaler following all state and federal regulations. (*Refer to Figure 21 - A at the end of this section.*)

3.3. Additional DEA 222 (Order) Forms can be obtained by EITHER:

3.3.1. Completing the preprinted reorder form that is enclosed with your forms and mailing it to the DEA in the self-addressed envelope, OR

3.3.2. Calling the DEA's automated request line at (800) 882-9539 and selecting Option "5."

3.4. In addition, note the following:

3.4.1. STORE all unused DEA 222 Forms in the store's Narcotic (CII) safe or cabinet.

3.4.2. USE the DEA 222 Forms in numerical sequence

3.4.3. Do NOT order bottles which contain quantities greater than 100 tablets/capsules.

3.4.4. Only the pharmacist who has signed a power of attorney for that pharmacy can sign the DEA 222 Form.

3.4.5. When the order is completed, place in a sealed envelope addressed to the wholesaler. Give the order to the driver or mail directly to the wholesaler.

3.4.6. File the store's copy of the completed DEA 222 Form in a binder or file drawer folder where they will be readily accessible to check in the order.

4. RECEIVING/CHECKING SCHEDULE II ORDERS

4.1. The following tasks must be performed by the pharmacist and cannot be delegated.

4.2. All Schedule II orders are received, checked in, and put away as follows:

4.2.1. RECEIVE the delivery from the wholesaler's driver.

4.2.2. RECONCILE the contents of the package (by item) to the wholesaler's invoice(s) in the presence of the driver.

4.2.3. IF there is a discrepancy: YOU MUST REFUSE THE ORDER.

4.2.3.1. If you have a patient waiting for an item in the order, please make every effort to service this patient by locating a

pharmacy which has the medication in stock (if the patient cannot wait until the correct order is received).

4.2.4. SIGN-OFF on the driver's receiving log if there are NO discrepancies.

4.2.5. RECORD the QUANTITY of each medication, and the DATE RECEIVED on each line on the DEA 222 Form. DITTO MARKS ARE NOT VALID.

Refer to Columns 8, 9, and 10 in Figure 21 - A.

4.2.5.1. If a packing slip comes with the merchandise, staple it to the back of the DEA 222 Form.

4.2.6. When the DEA 222 Form is completed, RECORD all medications received, and the signature of the receiving pharmacist, on the appropriate Schedule II Inventory Forms.

Refer to Figure 21 - C.

5. ESTABLISHING PERPETUAL INVENTORIES

5.1. A perpetual inventory for all Schedule II medications is established and then maintained on a daily basis.

5.2. Any change in the inventory levels of Schedule II medications is documented on that medication's Schedule II Inventory Form.

5.3. To establish the perpetual inventory, refer to Figure 21 - B at the end of this section.

5.4. In addition, note the following:

5.4.1. Use a SEPARATE Schedule II Inventory Form for each medication.

5.4.2. RECORD all entries in ink.

5.4.3. FILE the Inventory Forms in a CII Perpetual Inventory File Box.

5.4.4. To ensure the integrity of these records in the event of a burglary; do NOT store this file box where the Schedule II are kept such as in a narcotic security cabinet or safe.

6. FILLING SCHEDULE II PRESCRIPTIONS

6.1. Only the pharmacist is to retrieve, count or record the information on the Schedule II Inventory Form and put the medication back in stock.

6.2. All Schedule II prescriptions are to be double counted to ensure accuracy and are logged on the respective Schedule II Inventory Forms at the time that the prescription is filled.

6.2.1. Interns and/or Technicians, however, may be trained to process Schedule II prescriptions through the computer.

6.3. In addition, all pharmacists must adhere to the following:

6.3.1. All state and federal laws regarding the filling of Schedule II prescriptions **MUST** be followed by all pharmacy staff members.

6.3.2. Blanket decisions based on a practitioners prescribing habits or a customer's appearance are either unprofessional or illegal.

6.3.3. All prescriptions must be analyzed on an individual basis to determine their merit and medical necessity.

6.3.4. Every effort must be made to contact the physician when the legitimacy of a prescription is in doubt.

6.4. Workstation Responsibilities

6.4.1. DROP-OFF WORKSTATION

6.4.1.1. Accept prescriptions for CII narcotic medication

6.4.1.2. Perform data entry according to CVS policy

6.4.1.3. Once prescription is print ready, print the prescription label

6.4.1.3.1. If multiple prescriptions in order, print all prescriptions

6.4.1.4. Attach CII narcotic prescription hardcopy to corresponding prescription label with paper clip and provide to the Team Member at Production

6.4.2. PRODUCTION WORKSTATION

6.4.2.1. Place the CII narcotic prescription hardcopy to corresponding prescription label in the appropriate colored basket

6.4.2.1.1. If there are multiple prescriptions in order, prepare the remaining prescription(s) before providing to the Pharmacist

6.4.2.2. Place the basket in the Red Zone/To Be Verified Area in Promised Time priority order (Tower Format) for the QA Pharmacist

6.4.3. QUALITY ASSURANCE WORKSTATION

6.4.3.1. Prepare the CII narcotic prescription (QA Pharmacist only):

6.4.3.1.1. Obtain appropriate CII narcotic medication(s) from designated secure area

6.4.3.1.2. Perform Accuracy Scan for each medication

6.4.3.1.3. Count medication and label vial

6.4.3.1.4. Complete the CII narcotic log, file CII narcotic prescription, and return CII narcotic medication to designated secure area

6.4.3.1.5. Perform Quality Assurance verification

6.4.3.1.6. Bag the prescription(s) and place in Green Zone/Verified Area

6.4.4. PICK UP WORKSTATION

6.4.4.1. Adhere to the standard CVS Pick-up Workstation procedures

6.4.5. Failure to comply with these responsibilities may be considered a gross violation of company policy and may result in discipline up to and including termination

6.5. Refer to Figure 21 - C at the end of this section for step-by-step instructions for recording prescriptions on the inventory forms.

7. MONTHLY INVENTORIES

7.1. A physical inventory of all Schedule II medications is performed once a month by alternating pharmacists.

7.1.1. If possible, establish a routine where this inventory is completed the first Sunday of every month.

Note: A physical inventory of all Schedule II medications is performed once every 10 days in Massachusetts stores.

7.2. Any discrepancy between the physical inventory and perpetual Schedule II inventory form is reported to the DSM/Pharmacy Supervisor immediately.

7.2.1. The DSM/Pharmacy Supervisor will decide whether a DEA Form 106 Report will have to be filled out or not.

7.3. At no time is an adjustment made to an inventory form without the DSM's/Rx Supervisor's approval.

7.3.1. This includes burglaries, robberies, etc.

7.4. Include as part of the inventory all damaged and outdated products that have not been written off the inventory.

7.5. Refer to Figure 21 - C at the end of this section for step-by-step instructions.

8. BROKEN TABLETS

8.1. Segregate broken tablets into separate bottles by brand and either:

8.1.1. INCLUDE them as part of the perpetual inventory

8.1.2. WRITE them off the perpetual inventory:

8.1.2.1. ESTIMATE as closely as possible the number of broken tablets in each bottle.

8.1.2.2. SEAL the bottle with tape. Write on the outside "Broken Tablets."

8.1.2.3. MAINTAIN a separate inventory card for each brand of broken tablets.

8.1.2.4. STORE broken tablets with other outdated/damaged Schedule II merchandise.

8.2. Refer to Figure 21 - D at the end of this section for an example of this procedure.

9. OUTDATED SCHEDULE II (CII) RETURNS

Refer to Section 31: Merchandise Returns/Credit for the correct procedures to return damaged/outdated Schedule II drugs.

10. NARCOTIC (CII) CABINETS

10.1. The storage of all Schedule II medications is to meet the minimum standards established by state and federal laws.

10.2. Narcotic (CII) cabinets must be used when available. At no time are items other than Schedule II medications and unused DEA 222 Forms to be kept in these cabinets.

Access to the cabinet is restricted to the registered pharmacist(s) on duty only.

10.2.1. KEEP Narcotic (CII) cabinets LOCKED at all times except when retrieving, inventorying, stocking, or returning medications to the cabinet.

10.2.2. RESTRICT possession of CABINET KEYS to the store's regular pharmacist, the DSM/Pharmacy Supervisor, and the Floaters.

10.2.2.1. A key for floaters will be secured in a sealed control key envelope in the Front Store safe if the cabinet lock cannot be "keyed" with the gate and department doors.

10.2.2.1.1. The floater must seal the key in a new control envelope and sign it.

10.2.2.1.2. Any deviation from this policy must be reported to the DSM/Pharmacy Supervisor.

10.2.2.2. Keys are never left in the lock and should be properly secured when not in use.

10.2.3. The narcotic (CII) cabinet is closed and locked prior to leaving the store at closing.

11. COMBINATION NARCOTIC SAFES

Access to the safe is restricted to the registered pharmacist on duty only.

11.1. KEEP safe LOCKED at all times except when retrieving, inventorying, stocking, or returning medication to the safe.

11.2. NEVER leave the tumblers in the position where a slight turn of the tumbler would open the safe.

11.2.1. A safe is considered "open" unless the entire combination number is required to open it.

11.3. RESTRICT the safe's combination to the store's regular pharmacist, the DSM/Pharmacy Supervisor, Zone Scheduler and designated Floaters.

11.3.1. Floaters obtain the combination from:

11.3.1.1. The DSM/Pharmacy Supervisor or zone scheduler.

11.3.1.2. The envelope kept in the front store safe which contains the gate key.

11.3.1.3. CII Perpetual Inventory Box.

11.4. Floaters MUST maintain the integrity and confidentiality of this combination.

11.5. In stores where the combination tumbler is equipped with a key lock:

11.5.1. The key is never left in the lock.

11.5.2. The key control procedures are the same as those for locked narcotic cabinets.

11.6. The safe must be closed and locked prior to leaving the store at closing. (Unlock the rigid dial then spin it.)

12. COMBINATION NARCOTIC SAFES

Access to the safe is restricted to the registered pharmacist on duty only.

12.1. KEEP safe LOCKED at all times except when retrieving, inventorying, stocking, or returning medication to the safe.

12.2. NEVER leave the tumblers in the position where a slight turn of the tumbler would open the safe.

12.2.1. A safe is considered “open” unless the entire combination number is required to open it.

12.3. RESTRICT the safe’s combination to the store’s regular pharmacist, the DSM/Pharmacy Supervisor, Zone Scheduler and designated Floaters.

12.3.1. Floaters obtain the combination from:

12.3.1.1. The DSM/Pharmacy Supervisor or zone scheduler.

12.3.1.2. The envelope kept in the front store safe which contains the gate key.

12.3.1.3. CII Perpetual Inventory Box.

12.4. Floaters MUST maintain the integrity and confidentiality of this combination.

12.5. In stores where the combination tumbler is equipped with a key lock:

12.5.1. The key is never left in the lock.

12.5.2. The key control procedures are the same as those for locked narcotic cabinets.

12.6. The safe must be closed and locked prior to leaving the store at closing. (Unlock the rigid dial then spin it.)

13. COMBINATION/KEY NARCOTIC SAFES

Safes that utilize a key in conjunction with a combination lock may leave the combination component unlocked during the business day. However, the key component must be locked at all times and the must be removed from the lock. The key must be stored in a secure location, under the direct control of the pharmacist on duty.

14. AUDITS

Only the pharmacist on duty is allowed to verify Schedule II inventory counts during a pharmacy audit.

15. PHYSICAL INVENTORIES

15.1. The following must be done during a physical inventory:

15.1.1. For stores where CII drugs are dispersed throughout the shelves, ALLOW the inventory crew member to scan the CII's with the rest of the drugs.

15.1.2. For stores where CII drugs are kept in a cabinet or safe, OBSERVE the inventory crew member scan the CII drugs.

15.2. Remember, the pharmacist is responsible for the security of all CII medications during the inventory procedure.

16. BIENNIAL CONTROL SUBSTANCE INVENTORY

16.1. All pharmacies are required by law to take a Biennial Control Substance inventory upon the initial opening of the pharmacy and then subsequently on May 1 of every odd year.

16.2. Complete the Biennial Control Substance Inventory as follows:

16.2.1. FILL out the top of the inventory form completely. It is important that the pharmacist completing the inventory DATE and SIGN EACH SHEET.

16.2.2. COUNT all Schedule II substances first. An ACTUAL count is required on all Schedule II tablets and capsules. Powders must be weighed and liquids measured.

16.2.3. COUNT all Schedule III's, IV's, and V's after the Schedule II's. An estimated count is allowed for all Schedule III, IV and V substances.

16.2.4. The inventory sheet has multiple columns, which means that for subsequent inventories, it will only be necessary to put the date, time, signature, and printed name of the pharmacist taking the inventory on each sheet.

16.2.5. ADD any products which are not listed on the form.

16.2.6. KEEP the pharmacy copy of the Biennial Control Substances Inventory in the two-drawer filing cabinet as indicated on page 16 - 6 of this manual.

Figure 21 - A

DEA FORM 222		FORM 222		FORM 222	
NAME OF PURCHASER		NAME OF SUPPLIER		NAME OF SUPPLIER	
CITY AND STATE		CITY AND STATE		CITY AND STATE	
1	2	3	4	5	6
7	8	9	10	11	12
13	14	15	16	17	18
19	20	21	22	23	24
25	26	27	28	29	30
31	32	33	34	35	36
37	38	39	40	41	42
43	44	45	46	47	48
49	50	51	52	53	54
55	56	57	58	59	60
61	62	63	64	65	66
67	68	69	70	71	72
73	74	75	76	77	78
79	80	81	82	83	84
85	86	87	88	89	90
91	92	93	94	95	96
97	98	99	100	101	102
103	104	105	106	107	108
109	110	111	112	113	114
115	116	117	118	119	120
121	122	123	124	125	126
127	128	129	130	131	132
133	134	135	136	137	138
139	140	141	142	143	144
145	146	147	148	149	150
151	152	153	154	155	156
157	158	159	160	161	162
163	164	165	166	167	168
169	170	171	172	173	174
175	176	177	178	179	180
181	182	183	184	185	186
187	188	189	190	191	192
193	194	195	196	197	198
199	200	201	202	203	204
205	206	207	208	209	210
211	212	213	214	215	216
217	218	219	220	221	222
223	224	225	226	227	228
229	230	231	232	233	234
235	236	237	238	239	240
241	242	243	244	245	246
247	248	249	250	251	252
253	254	255	256	257	258
259	260	261	262	263	264
265	266	267	268	269	270
271	272	273	274	275	276
277	278	279	280	281	282
283	284	285	286	287	288
289	290	291	292	293	294
295	296	297	298	299	300
301	302	303	304	305	306
307	308	309	310	311	312
313	314	315	316	317	318
319	320	321	322	323	324
325	326	327	328	329	330
331	332	333	334	335	336
337	338	339	340	341	342
343	344	345	346	347	348
349	350	351	352	353	354
355	356	357	358	359	360
361	362	363	364	365	366
367	368	369	370	371	372
373	374	375	376	377	378
379	380	381	382	383	384
385	386	387	388	389	390
391	392	393	394	395	396
397	398	399	400	401	402
403	404	405	406	407	408
409	410	411	412	413	414
415	416	417	418	419	420
421	422	423	424	425	426
427	428	429	430	431	432
433	434	435	436	437	438
439	440	441	442	443	444
445	446	447	448	449	450
451	452	453	454	455	456
457	458	459	460	461	462
463	464	465	466	467	468
469	470	471	472	473	474
475	476	477	478	479	480
481	482	483	484	485	486
487	488	489	490	491	492
493	494	495	496	497	498
499	500	501	502	503	504
505	506	507	508	509	510
511	512	513	514	515	516
517	518	519	520	521	522
523	524	525	526	527	528
529	530	531	532	533	534
535	536	537	538	539	540
541	542	543	544	545	546
547	548	549	550	551	552
553	554	555	556	557	558
559	560	561	562	563	564
565	566	567	568	569	570
571	572	573	574	575	576
577	578	579	580	581	582
583	584	585	586	587	588
589	590	591	592	593	594
595	596	597	598	599	600
601	602	603	604	605	606
607	608	609	610	611	612
613	614	615	616	617	618
619	620	621	622	623	624
625	626	627	628	629	630
631	632	633	634	635	636
637	638	639	640	641	642
643	644	645	646	647	648
649	650	651	652	653	654
655	656	657	658	659	660
661	662	663	664	665	666
667	668	669	670	671	672
673	674	675	676	677	678
679	680	681	682	683	684
685	686	687	688	689	690
691	692	693	694	695	696
697	698	699	700	701	702
703	704	705	706	707	708
709	710	711	712	713	714
715	716	717	718	719	720
721	722	723	724	725	726
727	728	729	730	731	732
733	734	735	736	737	738
739	740	741	742	743	744
745	746	747	748	749	750
751	752	753	754	755	756
757	758	759	760	761	762
763	764	765	766	767	768
769	770	771	772	773	774
775	776	777	778	779	780
781	782	783	784	785	786
787	788	789	790	791	792
793	794	795	796	797	798
799	800	801	802	803	804
805	806	807	808	809	810
811	812	813	814	815	816
817	818	819	820	821	822
823	824	825	826	827	828
829	830	831	832	833	834
835	836	837	838	839	840
841	842	843	844	845	846
847	848	849	850	851	852
853	854	855	856	857	858
859	860	861	862	863	864
865	866	867	868	869	870
871	872	873	874	875	876
877	878	879	880	881	882
883	884	885	886	887	888
889	890	891	892	893	894
895	896	897	898	899	900
901	902	903	904	905	906
907	908	909	910	911	912
913	914	915	916	917	918
919	920	921	922	923	924
925	926	927	928	929	930
931	932	933	934	935	936
937	938	939	940	941	942
943	944	945	946	947	948
949	950	951	952	953	954
955	956	957	958	959	960
961	962	963	964	965	966
967	968	969	970	971	972
973	974	975	976	977	978
979	980	981	982	983	984
985	986	987	988	989	990
991	992	993	994	995	996
997	998	999	1000	1001	1002
1003	1004	1005	1006	1007	1008
1009	1010	1011	1012	1013	1014
1015	1016	1017	1018	1019	1020
1021	1022	1023	1024	1025	1026
1027	1028	1029	1030	1031	1032
1033	1034	1035	1036	1037	1038
1039	1040	1041	1042	1043	1044
1045	1046	1047	1048	1049	1050
1051	1052	1053	1054	1055	1056
1057	1058	1059	1060	1061	1062
1063	1064	1065	1066	1067	1068
1069	1070	1071	1072	1073	1074
1075	1076	1077	1078	1079	1080
1081	1082	1083	1084	1085	1086
1087	1088	1089	1090	1091	1092
1093	1094	1095	1096	1097	1098
1099	1100	1101	1102	1103	1104
1105	1106	1107	1108	1109	1110
1111	1112	1113	1114	1115	1116
1117	1118	1119	1120	1121	1122
1123	1124	1125	1126	1127	1128
1129	1130	1131	1132	1133	1134
1135	1136	1137	1138	1139	1140
1141	1142	1143	1144	1145	1146
1147	1148	1149	1150	1151	1152
1153	1154	1155	1156	1157	1158
1159	1160	1161	1162	1163	1164
1165	1166	1167	1168	1169	1170
1171	1172	1173	1174	1175	1176
1177	1178	1179	1180	1181	1182
1183	1184</				

Figure 21 - B

DRUG: Rosical Tablet

NDG: 0003486020

MANUFACTURER: Roxane

SIZE: 100

RECEIVING

Date	Order Form #	Invoice #	Quantity	Name	Address	Rx #	Quantity	Balance	R Ph. Initials
2/28/97	Beginning Inventory		50					20	MCP
3/2/97	123356	658321	100					130	MCP
3/4/97				SMITH, JOHN	123 MAIN STREET	Rx 205166	30	100	SM
3/16/97	Inventory		100					100	MCP
3/17/97	Broken Tablets		5					95	MCP

DISBURSEMENT

Date	Order Form #	Invoice #	Quantity	Name	Address	Rx #	Quantity	Balance	R Ph. Initials

2 (Rev. 10/77) Form 95a (12/77) 200-100

BALANCE: Record the amount of the item on hand at that time.

R. PH. INITIALS: Initials of pharmacist doing the inventory.

C. RECORDING SCHEDULE II ORDERS

Example: On March 3rd, DEA - 222 #123456 (Invoice #654321) shows Roxicet Tablet 100's were received. The new balance in stock as of March 3 is now 130 tablets.

D. RECORDING SCHEDULE II PRESCRIPTIONS

Example: On March 4th, prescription #295974 was filled for 30 Roxicet and the balance is now 100 tablets.

Use computer generated CII Inventory Sticker to record the prescription on the Inventory Form.

E. RECORDING MONTHLY INVENTORIES

Example: On March 15th, a monthly inventory was taken showing the balance on hand is what it should be (100 tablets).

F. RECORDING BROKEN TABLETS/DAMAGED PRODUCT

Broken Tablets are maintained on two inventory cards - the perpetual inventory card and a separate inventory card for broken tablets only.

Perpetual Inventory Card:

DATE: Record the date that the tablets are to be subtracted from the inventory.

RECEIVING: Write BROKEN TABLETS in this space.

DISBURSEMENT
AMT: Record the number of broken tablets written off the inventory.

BALANCE IN STOCK: Subtract the figure in the amount column from the balance in stock. Record this new total.

R. PH. INITIALS: Initials of pharmacist who writes the tablets off the inventory.

Example: On March 17th, 5 broken tablets were recorded on the perpetual inventory card and subtracted from the inventory balance (95 tablets).

Approved By: _____ Date: _____

Department Officer

Approved By: _____ Date: _____

Director of Internal
Audit

CVS Corporation
One CVS Drive
Woonsocket, RI 02895